

REMARKS

Claims 1-12 remain under active prosecution in the present application. Claims 13-22 have been withdrawn in response to the Examiner's restriction requirement. Claims 1, 3, 7, 8 and 12 have been amended. Applicants respectfully assert that all amendments are supported by the original disclosure and do not introduce new matter. Moreover, Applicants further respectfully assert that the amendments merely clarify the scope of the claims.

Before considering the rejections in detail, the fundamental concepts of the present invention will be briefly reviewed. The present invention comprises a method of detecting biological materials in finished water. The method comprises analyzing a sample of finished water suspected of having a targeted biological agent, wherein the effects of the finished water on the targeted agent are determined. This permits selection of an appropriate antibody (or other molecular recognition element). Alternatively, the finished water sample may be treated with conditioning agents such as buffers or chelators such that the effects of finished water treatment are reversed or mitigated, thereby permitting detection by an antibody or other suitable molecular recognition element. The present invention thereby allows detection of biological agents that have been chemically altered by additives and chemicals in the water.

The present invention may use more than one antibody in which a second antibody having an enzymatic or other label is mixed with the water sample. The second antibody may be directed to a different epitope, increasing the reliability of the method, and decreasing the likelihood of false positive results. Alternatively, the second antibody may be directed towards the first antibody. The enzymatic reaction can then be detected. Depending on the label used, significant amplification may be achieved, yielding a highly sensitive detection method for biological agents in water.

In the subject Office Action dated September 8, 2005, the Examiner rejected claims 1-12 under 35 U.S.C § 112; claims 1-12 as anticipated under 35 U.S.C § 102, and claims 1-12 as obvious under 35 U.S.C § 103. These rejections are addressed in detail below.

Claim Objections

The Examiner has objected to an omission on page 5, paragraph [0016] of the disclosure, wherein the first sentence the word "are" is missing in the phrase, "molecular recognition and signal emission in assays_ generally understood." The specification has been amended such that the proper linking verb is present.

Claim Rejections - 35 USC §112 (second paragraph)

The Examiner has rejected Claims 1 - 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each rejection is addressed below.

The Examiner has rejected claim 1 as vague and indefinite because claim 1 recites the phrase "selecting at least one first molecular recognition element that identifies," finding it unclear if this is a separate step, because there is no semi-colon found at the end of the phrase before the next step. The Examiner has further found this claim indefinite, finding the term "that identifies," unclear as to what the recognition element is identifying and how it is doing the identifying. Applicants have addressed this concern by amending the claim. The amended claim now makes clear that the molecular recognition element is identifying a biological agent via binding to the biological agent in the sample. The appropriate punctuation has also been inserted into the claim.

The Examiner has rejected claim 7 as not having proper antecedent basis. The claim has been appropriately amended so that the term "said first molecular recognition elements," is now in singular form as found in claim 1.

The Examiner has rejected claim 8 as lacking antecedent basis in reciting the term "said first or second molecular recognition element." Claim 8 is now amended to be dependent on Claim 2, which provides proper antecedent basis.

The Examiner has rejected claim 12 as lacking antecedent basis. Claim 12 now depends from claim 11, which provides proper basis for the term "solid phase".

Claim Rejections - 35 USC § 102

The Pyle et al. Reference

The Examiner has further rejected claims 1 - 4, 6, 7 and 10 - 12 under 35 U.S.C. § 102(b) as being anticipated by Pyle et al. (US 5,821,066).

Pyle et al. teaches a rapid method for the detection, identification and enumeration of specific respiring microorganisms. The method includes steps of a) passing a microbial sample through a collecting device to capture the cells; b) adding to the collecting device a fluorochrome dye specific for the detection of respiring cells and allowing the dye to incubate; c) treating the collecting device with a reactive fluorescent antibody which reacts with a target microorganism of interest present in said microbial sample; d) mounting the collecting device for examination by fluorescence microscopy in which a suitable light system is used to excite the fluorochrome dye and fluorescent antibody to fluoresce; and e) quantifying the respiring cells. Alternative embodiments include the use of immunomagnetic beads and other means of cell capture, and employing fluorescent oligonucleotide probes rather than fluorescent antibodies.

Applicant respectfully traverses the present rejection on the basis that the legal standard for anticipation is not met. Under 35 U.S.C. § 102(b), a claim is anticipated "only if each and every

element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, (Fed. Cir. 1987). Thus, for the references cited by the Examiner to anticipate the present invention under 35 U.S.C. 102(b), the reference must teach each and every element of the present invention.

The Examiner has accurately noted that the method taught by Pyle may be used for finished water (see column 6, ln 5-8), but failed to appreciate that Pyle does not teach a critical aspect of the present invention—that is, determining the effects of finished water prior to selecting an appropriate recognition element.

To fully understand the deficiencies of the Pyle reference (and the Fritsch reference, discussed below), a few key distinctions must be highlighted. First, “finished water” is very different from “potable water.” This distinction is key to understanding the present invention and the prior art references. “Potable,” (referred to in the Pyle reference at column 6, ln 52) is defined by the Merriam-Webster online dictionary as “suitable for drinking.” Applicants submit that this is the meaning of the term as understood by one skilled in the art. The present invention, in contrast, is not concerned with potable water per se, but rather, is directed specifically towards a method of analyzing “finished water.” Finished water is typically potable water, but the converse is not necessarily true.

The present application defines “finished water” in paragraph [0017] as “potable water *that has been treated by a treatment plant*” in which “various additives to provide, for example, disinfection, nutrition, and/or maintenance of the water distribution system are often included.” Additives such as chlorine, chloramines, chlorine dioxide, ozone, and ultra violet light,

nutritional additives such as fluoride, and phosphates (added to control corrosion of the water distribution system) are often added. The term “potable water” does not specifically include water that has been treated, and does not necessarily have chemicals added. This distinction is key to understanding the difference between the present invention and the prior art references.

One skilled in the art will readily understand the problems inherent in analyzing finished water. Disinfectants applied to drinking water, for example, are well known to cause the microbial population to become injured. As a result, the microbes may remain infective to humans, but be poorly detected by standard procedures. Copper and chlorine, in particular, are known to interfere with detection of some microbes. This results in an underestimation of microbial population, creating the risk of unacceptable levels of contaminants in treated drinking water.

While some of the steps of the present invention are taught by Pyle, the Pyle reference does not teach the essential steps of determining the effect of finished water on the biological agent to be detected, thereafter selecting the appropriate detection element (“molecular recognition element”). As discussed above, a primary purpose of the present invention is to circumvent the effects of finished water treatment that prevent standard methods (such as that taught in Pyle and Fritsch) from accurately assaying contaminants in finished water. The method taught in Pyle does not reference or take into consideration the effects of chemical treatment on possible contaminants. Rather, Pyle teaches a method of detecting respiring microbes, regardless of whether the sample contains chemical additives or not. Using the method taught in Pyle, contaminants altered by the water treatment process would not be detected with the same accuracy as when analyzed using the present invention.

To reiterate, the present invention requires the additional step of determining the effects of the water treatment on the biological agent to be detected. Pyle does not teach this essential element, and therefore cannot anticipate the present invention.

In light of the deficiencies of Pyle et al with respect to the present invention, the rejection under 35 U.S.C. § 102 does not apply. Applicants therefore respectfully request that this rejection be withdrawn.

The Fritsch Reference

The Examiner has further rejected Claims 1 - 5 and 7 - 10 35 U.S.C. §102(e) as being anticipated by Fritsch et al. (US 2003/0108922).

In brief, Fritsch has similar deficiencies as the Pyle reference above. To briefly review the reference, Fritsch teaches a rapid, accurate and highly sensitive method for detecting water born pathogens. Specifically, pathogens such as bacteria are immobilized on a surface. Electro-labeling molecules are then non-covalently attached to the pathogens, then activated so as to generate a current that may be measured. The method is suitable for detecting a wide variety of pathogens, proteins, polynucleotides and a variety of other biological molecules, in particular *Cryptosporidium parvum*.

While Fritsch et al. teaches a method of detecting pathogens in water samples, Fritsch et al. does not teach the essential element of determining the effects of the finished water process on the biological agent to be measured. As discussed above, claim 1 of the instant application claims the essential element of determining the effects of the finished water sample on the biological agent prior to selecting a molecular recognition element (such as an antibody). Fritsch et al. does

not teach a method in which the effects of finished water on a biological agent are determined. Rather, Fritsch et al. teaches a detecting a pathogen in a water sample, regardless of whether the water is “finished water” or not.

As such, Fritsch et al. does not teach an essential element of independent claim 1, and cannot anticipate the present invention as a matter of law. Applicants respectfully request that the rejection be withdrawn.

Claim Rejections - 35 USC § 103

The Examiner has further rejected Claims 6, 11 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Fritsch et al. (US 2003/0108C22) in view of Pyle et al (US 5,821,066).

The Examiner bears the burden of establishing a prima facie case of obviousness. To make such a showing, the prior art reference, or references when combined, must teach or suggest all the claim limitations. MPEP § 2142.

In light of the teaching of Pyle and Fritsch, it is not possible for the Examiner to meet this burden. The combined disclosures of these references do not teach or suggest all the claim limitations of the present invention. Specifically, as discussed above, neither reference teaches the essential element of determining the effects of finished water on the biological agent to be detected. In light of this deficiency present in both references, it is not possible for these references to be combined to teach the present invention. Thus, one of ordinary skill in the art could not have combined the references so as to arrive at the present invention.

Applicants respectfully submit that the Examiner has not met the burden to show a prima facie case of obviousness. As such, Applicants respectfully submit that the rejection under 35 U.S.C § 103 be withdrawn.

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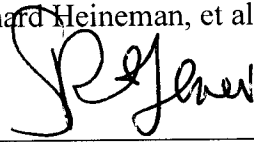
CONCLUSION

In light of the amendments and remarks made herein, it is respectfully submitted that the claims currently pending in the present application are in form for allowance. Accordingly, reconsideration of those claims, as amended herein, is earnestly solicited. Applicants encourage the Examiner to contact their representative, Stephen R. Albainy-Jenei at (513) 651-6839 or salbainyjenei@fbtlaw.com.

The Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully submitted,

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